

REMARKS

Claims 1-16 were pending at the time of this office action. Claim 1 has been amended. Thus, claims 1-16 are present for examination. Re-examination and reconsideration of the application, in view of the following remarks, are requested.

Claim Rejections – 35 U.S.C. § 102

Claims 1, 2, 3, 5, 6, 7, 8, 10, 12, 13, 14, and 16 stand rejected under 35 U.S.C. §102(b) as being anticipated by Tune, U.S. Patent No. 5,630,710. This rejection is respectfully traversed, as follows.

Claim 1 recites a medical system comprising an ambulatory medical device (MD) and a communication device (CD). The MD and CD in claim 1 are two distinct devices, connected for communication with each other, through respective telemetry systems, for example, a wireless telemetry system. In particular, the medical device comprises, among other features, at least one MD telemetry system and at least one MD processor that controls the medical device. The communication device comprises, among other features, at least one CD telemetry system and at least one CD processor that controls, at least in part, operation of the CD telemetry system and operation of the communication device. Claim 1 further recites that the CD telemetry system sends messages to or receives messages from the MD telemetry system. Thus, the CD and MD are two distinct devices, that communicate with each other through respective CD and MD telemetry systems.

Claim 1 recites features that are neither disclosed nor suggested in the prior art of record. For example, as discussed above, claim 1 recites that the medical device (MD) and the communication device (CD) each have a respective processor that controls its respective operation. For example, referring to the embodiment in figure 3 of the present application, the communication device 32 and the CD processor 42 are clearly distinct from the medical device 2 and the MD processor 72. Tune, on the other hand, does not disclose that the medical device 10 and the control panel 26 have separate processors, as is recited in claim 1. Indeed, Tune discloses that the control panel 26 (the communication device) is not distinct from the medical device. [Tune,

col. 22, Ins. 36-67, Figures 2 and 25.] Tune's figure 2, in particular, shows that the control panel 26 is part of the medical device 10. Thus, claim 1 recites features that are neither disclosed nor suggested in the prior art of record.

The office action suggests, at page 3, that Tune discloses that the communication device is controlled by at least one CD processor 576. However, Tune teaches that feature 576 is not a processor, but is an analog multiplexer. [Tune, col. 26, Ins. 34-40.] Tune teaches that the analog multiplexer 576 is connected to a bus 571 and is connected to I/O devices. [Tune, col. 26, Ins. 34-40.] Tune does not teach, in connection with the multiplexer 576 or elsewhere, that the communication device comprises at least one CD processor that controls operation of the CD telemetry system and operation of the communication device.

In addition, claim 1 recites that the medical device and the communication device each have separate telemetry systems and that the CD telemetry system sends messages to or receives messages from the MD telemetry system. These features are neither disclosed nor suggested in Tune. Indeed, because Tune teaches that the control panel 26 is physically connected to and a part of the medical device 10, Tune does not require multiple telemetry systems communicating with one another.

Because claim 1 recites features that are neither disclosed nor suggested in Tune, the rejection of claim 1 is respectfully traversed. Claims 2-5 are all dependent, directly or indirectly, on claim 1. Accordingly, the rejection of claims 2-5 is likewise traversed. Also, such dependent claims recite further features that are neither described nor suggested by Tune, as described below.

Independent claims 6 and 12 recite features as discussed above with respect to claim 1. Thus, the rejection of claims 6 and 12 is respectfully traversed for at least the reasons discussed above. Claims 7, 8, 10, 13, 14, and 16 are all dependent, either directly or indirectly, on claims 6 and 12. Thus, the rejection of claims 7, 8, 10, 13, 14, and 16 is likewise traversed. Also, such dependent claims recite further features that are neither described nor suggested by Tune, as described below.

In addition, claim 2 recites further features that are neither disclosed nor suggested in Tune. For example, claim 2 recites, among other features, that a first

portion of the CD telemetry system is incorporated into the CD processor and that a second portion of the CD telemetry system is external to the CD processor. As discussed above, Tune does not disclose or suggest employing a separate processor for the communication device. Moreover, Tune does not disclose or suggest a communication device employing a separate telemetry system, nor does Tune disclose or suggest employing a telemetry system that includes two portions. Accordingly, claim 2 recites features that are neither disclosed nor suggested in Tune. The rejection of claim 2 is respectfully traversed.

Claim 7 and 13 also recite such further features as discussed in connection with claim 2. Thus, for at least the reasons discussed in connection with claim 2, the rejection of claims 7 and 13 is respectfully traversed.

Claim 3 recites further features that are neither disclosed nor suggested in Tune. For example, claim 3 recites that the MD electronic control circuitry comprises at least one external MD functional module. Applicant has carefully reviewed the Tune reference and applicant does not believe that the medical device electronic control circuitry disclosed in Tune comprises at least one external medical device functional module. The medical device disclosed in Tune is shown in figure 2. It is evident from that figure that the electronic control circuitry does not comprise at least one external functional module. Claim 3 alternately recites that the CD electronic control circuitry comprises at least one external CD functional module. As discussed above, Tune discloses that the communication device is part of the medical device. Accordingly, Tune does not disclose the communication device comprising a separate communication device processor, nor does Tune disclose a functional module that is external to the communication device processor. Claim 3 alternately recites that the MD processor comprises an internal MD CPU and at least one other internal MD functional module. Applicant has reviewed the Tune reference and applicant does not believe that Tune discloses at least one other internal MD functional module. Finally, claim 3 alternately recites that the CD processor comprises an internal CD CPU and at least one other internal CD functional module. As discussed above, Tune does not disclose the communication device comprising a separate processor (CPU). Tune also does not disclose a communication device processor comprising the at least one other

internal communication device functional module. Accordingly, claim 3 recites features that are neither disclosed nor suggested in the prior art of record. The rejection of claim 3 is respectfully traversed.

Claims 8 and 14 recite features as discussed in connection with claim 3. Thus, for at least the reasons discussed in connection with claim 3, the rejection of claims 8 and 14 is likewise traversed.

Claims 12 and 15 stand rejected under 35 U.S.C. §102(b) as being anticipated by Snell, U.S. Patent No. 5,759,199.

The rejection of claims 12 and 15 is respectfully traversed.

Claim 12 recites features that are neither disclosed nor suggested in Snell. For example, claim 12 recites that the CD display is controlled to depict a plurality of patient programmable options, wherein at least one of the patient programmable options may be enabled or disabled, such that when disabled, the at least one patient programmable option is no longer displayed as an option. These features are neither disclosed nor suggested in Snell. Applicant has carefully reviewed the Snell reference, and has found no disclosure or suggestion by Snell of enabling or disabling options and displaying only enabled options. Thus, Snell does not disclose each of the features recited in claim 12. The rejection of claim 12 is respectfully traversed.

Claim 15 is dependent on claim 12. Thus, for at least the reasons discussed above, the rejection of claim 15 is respectfully traversed.

Claims 1, 4, 6, and 9 stand rejected under 35 U.S.C. §102(e) as being anticipated by Hartlaub, U.S. Patent Application, Pub. No. U.S. 2001/0037083A1.

The rejection of claims 1, 4, 6, and 9 is respectfully traversed.

Claim 1 recites features that are neither disclosed nor suggest by Hartlaub. For example, claim 1 recites that the communication device comprises a display device that is controlled to show a plurality of infusion parameters simultaneously. These features are neither disclosed nor suggested in Hartlaub. Hartlaub merely teaches that an LCD display 304 may provide the patient with alarm, status and task information.

[Hartlaub, col. 3, ¶ 030.] Hartlaub does not disclose or suggest that the information may be displayed simultaneously, nor does the information amount to “a plurality of infusion parameters.” Thus, Hartlaub does not disclose or suggest the features recited in claim 1. The rejection of claim 1 is respectfully traversed.

Claim 6 recites features that are neither disclosed nor suggested in Hartlaub. For example, claim 6 recites that the communication device includes a CD display controlled by the at least one CD processor for providing a visual feedback to the patient, and wherein that feedback comprises a display of the quantity of a consumable estimated to be remaining in the system. These features are neither disclosed nor suggested in Hartlaub. Hartlaub merely discloses that the patient controller 310 may contain an LCD display 304. Hartlaub does not teach, disclose, or suggest that the LCD display comprises a display of the quantity of a consumable estimated to be remaining in the system. Thus, Hartlaub does not disclose the features recited in claim 6. The rejection of claim 6 is respectfully traversed.

Claims 4 and 9 are dependent on claims 1 and 6, respectively. Thus, for at least the reasons discussed above, the rejection of claims 4 and 6 is likewise traversed.

Claim Rejections – 35 U.S.C. § 103

Dependent claim 11 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Tune, as applied to claims 1-10 and 12-16, and further in view of Er, U.S. Patent No. 6,185,461.

The rejection of claim 11 is respectfully traversed.

Dependent claim 11 recites that a consumable is either (1) battery power remaining in a replaceable CD battery in the communication device, wherein a voltage level on the CD battery is graphically depicted with a desired resolution, or (2) battery power remaining in an MD battery in the medical device, wherein a voltage level on the battery is graphically depicted with a desired resolution. Tune does not disclose or suggest employing a display device to monitor power remaining in a battery. The office action suggests that Er corrects the defects of Tune. Er, however, is directed to a system and method for verification of recommended replacement time indication (for a battery) in an implantable cardiac stimulation device. Thus, there is no motivation or

suggestion, in either Tune or Er, to combine the references. Er teaches employing a device that may be "interrogated" by an external programmer to determine whether a recommended replacement time indicator in the device is accurately set. [Er, Abstract.] Not only is there is no motivation or suggestion, in either Tune or Er, to combine the references, but the references also do not teach how they could be combined to give rise to features recited in claim 11. Thus, the rejection of claim 11 is respectfully traversed.

Double Patenting

The office action suggests that claims 1-16 of this application conflict with the claims of other applications. The applicant submits that the claims in the cited applications are indeed distinct and are not in conflict with the present claims. Although the claims in the various applications recite some common features, the claims also recite features that distinguish them from one another.

The claims of the present application include features not present in claims of the other applications and, thus, are distinct from and not in conflict with the claims of the claims of the other applications. For example, in the present application, claims 1-5 recite a medical system comprising, *inter alia*, an ambulatory medical device, a communication device, an infusion pump, and a display simultaneously showing a plurality of infusion parameters. Claims 6-11 recite, for example, a medical system comprising, *inter alia*, an ambulatory medical device, a communication device, and a display controlled by at least one communication device processor and providing visual feedback of a quantity of a consumable estimated to be remaining in the system. Claims 12-16 recite, for example, a medical system comprising, *inter alia*, an ambulatory medical device, a communication device, and a display depicting a plurality of patient programmable options which may be enabled or disabled.

Also, claims in the 09/768,194 application include features not present in the claims of the present application. For example, claims 1-9 recite a medical system comprising, *inter alia*, an ambulatory medical device, a communication device, and a stack used in conjunction with a central processing unit. Claims 10-19 recite, for example, a medical system comprising, *inter alia*, an ambulatory medical device, a

communication device, and a watchdog circuit causing at least one medical device to undergo a predefined process.

Claims in the 09/768,044 application include features not present in the claims of the present application. For example, claims 1-14 recite a medical system comprising, *inter alia*, an ambulatory medical device, a communication device, and a reservoir, wherein the medical device changes modes, in part, based on an amount of drug remaining in the reservoir. Claims 15-27 recite, for example, a medical system comprising, *inter alia*, an ambulatory medical device, a communication device, and a reservoir, wherein the reservoir provides at least two signals indicating reservoir level.

Claims in the 09/768,0197 application include features not present in the claims of the present application. For example, claims 20-28 recite a medical system comprising, *inter alia*, an ambulatory medical device, a communication device, and a reservoir, wherein the communication device can be programmed with at least two quantities relating to drug delivery and the medical device delivers a drug based on the quantities. Claims 29-40 recite, for example, a medical system comprising, *inter alia*, an ambulatory medical device and a communication device, wherein the medical device provides quantized amounts of treatment to the body of a patient or monitors the body of a patient and is configured with at least one treatment amount or monitoring amount accumulator.

Claims in the 09/768,210 application include features not present in the claims of the present application. For example, claims 6-16 recite a medical system comprising, *inter alia*, an ambulatory medical device, a communication device, and a watchdog circuit causing at least one medical device to undergo a predefined process. Claims 17-20 recite, for example, a medical system comprising, *inter alia*, an ambulatory medical device and a communication device, and a watchdog circuit having a watchdog monitor. Claims 21-25 recite, for example, a method for communicating with a medical device comprising, *inter alia*, providing an ambulatory medical device, sending message to or receiving messages from the medical device telemetry system via a communication device, and causing the communication device to undergo a predefined process.

Claims in the 09/768,221 application include features not present in the claims of the present application. For example, claims 1-7 recite a medical system comprising, *inter alia*, an ambulatory medical device, a communication device, a medical device alarm and a communication device alarm. Claims 8-14 recite, for example, a medical system comprising, *inter alia*, an ambulatory medical device and a communication device, wherein the medical device or the communication device clears selected alarm conditions without removing the alarm conditions. Claims 15-22 recite, for example, a medical system comprising, *inter alia*, an ambulatory medical device and a communication device, wherein the medical device or the communication device presents a plurality of alarm conditions. Claims 23-30 recite, for example, a medical system comprising, *inter alia*, an ambulatory medical device and a communication device, wherein the medical device or the communication device has an alarm activated in response to a selected condition. Claims 31-39 recite, for example, a medical system comprising, *inter alia*, an ambulatory medical device and a communication device, wherein the medical device processor uses a stack in conjunction with a central processing unit. Claims 40-49 recite, for example, a medical system comprising, *inter alia*, an ambulatory medical device and a communication device, wherein a medical device watchdog circuit cases a medical device processor to undergo a predefined process.

Claims in the 09/768,204 application include features not present in the claims of the present application. For example, claims 1-17 recite a medical system comprising, *inter alia*, an ambulatory medical device and a communication device, wherein the communication device ways no more than about 10 oz. Claims 18-33 recite, for example, a medical system comprising, *inter alia*, an ambulatory medical device and a communication device, wherein the communication device receives status information on the medical device battery. Claims 34-39 recite, for example, a medical system comprising, *inter alia*, an ambulatory medical device and a communication device, wherein the communication device is programmed to allow entry of delivery quantities.

Claims in the 09/768,208 application include features not present in the claims of the present application. For example, claims 1-52 recite a medical system

comprising, *inter alia*, an ambulatory medical device and a communication device, wherein the medical device processor comprises at least two processors.

Claims in the 09/768,199 application include features not present in the claims of the present application. For example, claims 1-20 recite a medical system comprising, *inter alia*, an ambulatory medical device and a communication device, wherein at least one medical device processor includes an application specific integrated circuit. Claims 21-43 recite, for example, a medical system comprising, *inter alia*, an ambulatory medical device and a communication device, wherein the medical device requires activation to perform an intended function.

Claims in the 09/768,198 application include features not present in the claims of the present application. For example, claims 1-16 recite a medical system comprising, *inter alia*, an ambulatory medical device, a communication device, and a display having a bit map region for displaying selected information. Claims 17-24 recite, for example, a medical system comprising, *inter alia*, an ambulatory medical device, a communication device, and a display having at least one icon. Claims 25-39 recite, for example, a medical system comprising, *inter alia*, an ambulatory medical device, a communication device, and a display having a moving image which graphically depicts system status.

Claims in the 09/768,193 application include features not present in the claims of the present application. For example, claims 1-21 recite a medical system comprising, *inter alia*, an ambulatory medical device and a communication device, wherein the medical device and the communication device include a plurality of electronic modules, at least one of which is switched from an active state to a power saving state when not in use and switched to an active state when needed a portion of the time.

Accordingly, the claims of the present application are patentably distinct from and not in conflict with claims of the other cited application. Accordingly, no claims have been cancelled. In addition, for the same reason, the provisional rejection under the judicially created doctrine of obviousness type double patenting is respectfully traversed.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance. Reexamination and reconsideration of the application, and allowance of the claims at an early date, are respectfully requested.

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